UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE OCULAR THERAPEUTIX, INC. SECURITIES LITIGATION This Document Relates To: All Actions	No. 1:17-cv-12288-GAO **ORAL ARGUMENT REQUESTED** Leave to File Excess Pages Granted on July 2, 2018

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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I. INTRODUCTION

Plaintiffs' detailed factual allegations set out a classic case of securities fraud. Throughout the Class Period,[1] Defendants[2] assured investors that Ocular's manufacturing of its flagship drug candidate, Dextenza, complied with U.S. Food & Drug Administration (the "FDA") requirements and that manufacturing issues for Dextenza were, and would be, adequately and timely resolved. Defendants, however, withheld from investors material adverse information communicated to Defendants by the FDA, as detailed in two separate Form 483s that identified striking deficiencies and defects in the manufacturing of Dextenza and made clear that in fact Ocular's manufacturing operations were not even close to being in compliance with FDA requirements. Without curing these deficiencies, which Defendants knew that they could not and would not do, the chances of receiving FDA approval were nil. Nevertheless, Defendants continued to conceal those facts and misrepresent their compliance with the FDA's requirements. These misrepresentations went to the heart of Ocular's business and the basis upon which investors valued the manufacturing-stage drug company: the prospects and timeline of obtaining FDA approval of the New Drug Application ("NDA") for the commercialization of Dextenza.

In the face of these thorough allegations, none of Defendants' arguments stand up to scrutiny.[3] Defendants cannot escape that they repeatedly misrepresented that Ocular's facilities adhered to "good manufacturing practices, or cGMP." ¶¶ 67, 73. These misrepresentations were

[1] The Class Period is March 10, 2016 through July 11, 2017, inclusive. *See* Dkt. No. 63, Plaintiffs' Consolidated Amended Class Action Complaint (the "Complaint"), at ¶ 1. Unless otherwise stated, all "¶__" citations herein refer to the Complaint.

[2] Defendants include Ocular Therapeutix, Inc. ("Ocular" or the "Company") and Individual Defendants Amarpreet Sawhney ("Sawhney') and Eric Ankerud ("Ankerud"). Plaintiffs do not contest the Motion as it relates to defendants George Migausky and Andrew Hurley.

[3] Found in the memorandum of law in support (Dkt. No. 67, cited herein as the "Motion" or the "MTD") of Defendants' motion to dismiss the Complaint (Dkt. No. 66).

material because the FDA issued at least two Form 483s to Defendants that identified numerous ways in which Ocular's practices fell far short of and violated those standards, which in turn severely endangered the chances that the FDA would approve the Dextenza NDA absent a massive overhaul of Ocular's manufacturing operations. Similarly, Defendants' assurances that any manufacturing issues observed by the FDA could be remedied "in a timely manner" (¶¶ 75, 79) were misleading because the manufacturing issues were so significant they could not be (and were not) remedied prior to the FDA rejecting the Company's Dextenza NDA. Nor can Defendants whitewash their misrepresentations and omissions by claiming their statements were forward-looking and protected by the PLSRA's safe harbor. Defendants' repeated misrepresentations that its manufacturing processes complied with the FDA's requirements were statements about the existing state of affairs, not about the future.

Defendants' claim that they lacked requisite scienter also lacks merit. The Individual Defendants were the *designated recipients* of the crucial Form 483s at issue. Moreover, the Individual Defendants were top executives of a relatively small company, making it unlikely – if not impossible – that they were not aware of the Form 483s, Ocular's manufacturing problems, and/or the implications of the same for the approval of Dextenza. Further, Dextenza was Ocular's principal drug candidate; under the "core operations" doctrine, the Individual Defendants are deemed to have knowledge of material information pertaining to it. The U.S. Securities and Exchange Commission's ("SEC") investigation of Ocular further strengthens an inference of scienter. Finally, a highly placed confidential witness ("CW") has revealed that Ankerud admitted that Ocular's NDA resubmission would not meet FDA standards.

In sum, the Complaint meets – and exceeds – the PLSRA's pleading requirements. The Court should deny Defendants' motion in its entirety.

II. STATEMENT OF RELEVANT FACTS

A. Background of Ocular and Dextenza

Ocular is a biopharmaceutical company specializing in the development and commercialization of therapies for diseases and conditions of the eye. ¶ 23. During the Class Period, Ocular was focused primarily on the development and commercialization of its lead product candidate, Dextenza. ¶¶ 23, 102. Dextenza is a medical implant and requires a sterile drug manufacturing process, thus Ocular's manufacturing facility is subject to sterile drug manufacturing requirements under FDA-regulated "current good manufacturing practices" ("cGMP"). ¶¶ 23, 25, 27.

B. Significance of cGMP Regulations in the FDA Review and Approval Process and the FDA's Use of "Form 483"

cGMP regulations contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. ¶ 27. Part of the FDA's approval process for new drug and device applications is a review of the manufacturer's compliance with the cGMP. ¶ 28. Ocular, in its Form 10-K dated March 10, 2016 (the "2015 Form 10-K"), acknowledged that it "must comply with federal, state and foreign regulations, including quality assurance standard applicable to medical device and drug manufacturers, such as cGMP, which is enforced by the FDA through its facilities inspection program." ¶ 27. The FDA uses a Form 483 to notify drug manufacturers of objectionable conditions and practices observed during a drug manufacturing facility's inspection.[4] ¶ 29. A company's receipt of a Form 483 identifying serious problems in its practices relating to drug manufacturing reasonably

[4] Defendants attempt to downplay a Form 483's significance. MTD at 3, n.3. But a Form 483 notifies a company's management of *objectionable* conditions and is not intended to be an all-inclusive list of every possible deviation from law and regulation that exists at time of inspection. FDA, "FDA Form 483 Frequently Asked Questions," https://www.fda.gov/ICECI/Inspections/ucm256377.htm (last assessed Sept. 3, 2018).

may expect that such problems must be resolved prior to obtaining FDA approval to manufacture and market the drug. *Id.*

C. Ocular's Recurring – and Undisclosed – Dextenza Manufacturing Deficiencies and Defects Plague the Commercialization Process

1. Ocular's September 2015 New Drug Application and the February 2016 Form 483 Documenting Serious Manufacturing Problems

Prior to the Class Period, in September 2015, Ocular submitted an NDA to the FDA in which it sought approval of Dextenza for treatment of ocular pain following ophthalmic surgery. ¶ 30. The FDA accepted the NDA for review and established a target date for action on the application under the Prescription Drug User Fee Act ("PDUFA") of July 24, 2016. *Id.*

After accepting Ocular's September 2015 NDA for approval, the FDA inspected Ocular's manufacturing facility in February 2016 and identified numerous major problems with the Company's manufacturing process. ¶¶ 5, 30. On February 11, 2016, after the inspection, the FDA issued a Form 483 ("February 2016 Form 483") to Defendants, listing ten observations concerning areas where Ocular failed to comply with cGMP. ¶¶ 5, 31, 43.

Observation 1 noted that Ocular's analysis documentation submitted in connection with its NDA was deficient because it only retained, and included in its analysis, reprocessed data from its testing. ¶ 33. The FDA requires the use of original testing data for the analyses on which a company bases its NDA, and such data must be retained for verification by FDA inspectors for accuracy. *Id.* This observation effectively required Ocular to redo its testing and analysis of Dextenza. *Id.* A subpart of Observation 1 noted that in the review of the reprocessed data, the Company failed to incorporate data relating to a particular, regularly occurring impurity in its overall purity analysis of Dextenza. ¶ 34. Resolution of this failure would likely have

prevented future contamination issues discussed in detail below.[5]

Observation 2 noted that Ocular's procedure for sampling drug products for conformity with written specifications improperly failed to ensure that samples were representative. ¶ 36. Observation 3 further stated "control procedures [to] monitor outputs and validate manufacturing processes responsible for causing variability in the in-process materials and the drug product" were not established. ¶ 37. Indeed, the control procedures failed to ensure the most basic elements of drug preparation, including adequate mixing to achieve product consistency during bulk preparation. *Id.* A subpart of Observation 3 also noted that the Company did not document potentially defective drug batches or investigate why they were potentially defective. ¶ 38. This type of documentation and investigation is necessary in order to reduce the occurrence of defects, such as particulate contamination in the drug product. *Id.*

Observation 4 made clear that certain discrepancies in yields demonstrated a "lack of accountability for the full formulated batch quantity, quality, and finished drug yield." ¶ 39. Observation 6 stated that "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity." *Id.* Observations 7 and 8 stated the Company lacked adequate equipment to prevent product contamination and microorganism growth. *Id.* Ocular also failed to establish time limits for safely storing the product and appropriate storage temperature. *Id.*

While Defendants stated in their 2015 Form 10-K that they "received an FDA Form 483 containing inspectional observations," they simultaneously *significantly downplayed the*

[5] Another notable subpart of Observation 1 found that Ocular lacked "written procedures specifying how manual integration of chromatograms is performed." ¶ 35. Documentation of such procedures is vital for the FDA's evaluation of the reliability and reproducibility of Ocular's analysis of Dextenza – a major review point for any NDA. *Id.*

significance of the observations received. ¶¶ 6, 43-44. These observed deficiencies would require Ocular to revise key manufacturing procedures, including those related to product testing and sampling, and *resubmit its analysis for the NDA for Dextenza*. ¶ 44.

2. July 2016 Complete Response Letter

In July 2016, Ocular received a complete letter response ("CRL") rejecting Ocular's Dextenza NDA, citing certain unresolved deficiencies in manufacturing process raised in the February 2016 Form 483. ¶¶ 6, 32, 45. On July 25, 2016, Ocular issued a press release announcing its receipt of the CRL from the FDA and the FDA's refusal to grant approval of Ocular's NDA for Dextenza based on "deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection[.]" ¶¶ 45, 84. On this news, Ocular's share price fell $0.75, or 14.51%, on July 25, 2016. ¶ 85.

3. January 23, 2017 NDA

On January 23, 2017, Ocular announced that it resubmitted its NDA for Dextenza. ¶ 46. About one month later, the Company announced that the FDA accepted for review its NDA resubmission for Dextenza with a PDUFA date of July 19, 2017. ¶¶ 7, 47. Prior to Ocular's January 2017 NDA, the CW had a direct conversation with Ankerud in which Ankerud *expressly acknowledged* that he and the Company knew Ocular would be including batch records in the January 2017 NDA resubmission that *would not meet FDA standards*. ¶ 46.

4. Ocular's May 2017 Form 483 Reiterates Serious Manufacturing Deficiencies and Identifies Additional Deficiencies, Which Defendants Downplay With the Goal of Reassuring Investors

The FDA re-inspected Ocular's manufacturing facilities between April 24 and May 4, 2017. ¶ 48. Following this series of inspections, the FDA issued another Form 483 on May 4, 2017 (the "May 2017 Form 483"), identifying six inspectional observations rendering Ocular's manufacturing operations to be non-compliant with cGMP. *Id.*

Several of the May 2017 Form 483 observations repeated or expanded on deficiencies noted in the February 2016 Form 483. ¶ 49. For example, Observation 5 stated, "Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity"—repeating Observation 6 from the February 2016 Form 483 *almost verbatim*. ¶¶ 39, 55.

Observation 1 revealed that unknown and uninvestigated particulate matter had been found in 10 of 23 lots (more than 43%) manufactured from February 2016 (when the February 2016 Form 483 was issued) to May 2017. ¶ 50. The lots found to contain unknown particulate matter were released for intended commercial use. ¶ 51. Notably, Ocular failed to investigate the nature of this particulate matter until April 28, 2017—*i.e.*, during the course of the FDA's site inspection (*id.*), despite the FDA warning Defendants that the Company's procedures potentially missed detection of defects, including particulate contamination in the drug product in a subpart of Observation 3 from the February 2016 Form 483 (¶ 38).

Observation 3 noted that, "There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, purity they purport or are represented to possess." ¶ 53. Importantly, it continued: Ocular "ha[d] not systematically evaluated the lots manufactured from February 2016 to [May 2017.]" *Id.* In other words, even though the prior Form 483 observed, and warned Defendants, that (i) discrepancies in Ocular's yields demonstrated a "lack of accountability for the full formulated batch quantity, quality, and finished drug yield" (¶ 39); and (ii) "[c]ontrol procedures [we]re not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the

drug product" (¶ 37), Ocular had not remedied these issues by the time the May 2017 Form 483 was issued. In short, Ocular was not cGMP compliant *at any point* during the Class Period. Observation 4 expanded on the February 2016 Form 483 by detailing further blatant inadequacies in Ocular's controls, including failing to document "[t]he responsibilities and procedures applicable to the quality control unit" in writing. ¶ 54.

On May 5, 2017, Ocular issued a press release revealing that the FDA completed additional pre-NDA inspections of its manufacturing facility and had issued a new Form 483 detailing deficiencies in Ocular's manufacturing. ¶ 86. During a conference call held later that day, Sawhney acknowledged the FDA's recent inspection and Ocular's receipt of the May 2017 Form 483, but omitted the most critical problems identified in that Form 483 and downplayed the inspection results in reassuring investors that the Company *expected to be able to resolve the problems identified "in a timely manner*" (*i.e.*, by the July 19, 2017 PDUFA Action Date). ¶ 59. On this news, Ocular's share price fell $1.47, or 16.15%, on May 5, 2017. ¶ 87.

5. July 2017: *Seeking Alpha* Reveals the Gravity of the Form 483s; Ocular Receives a Second CRL

On July 6, 2017, the website *Seeking Alpha* published an article entitled, "Ocular: A Poke In The Eye." ¶¶ 9, 60, 88. The article made the contents of the February 2016 and May 2017 Form 483s public for the first time, and further described the very serious observations within the Form 483s, highlighting the repeated and increasing severity of the observations from the first to the second Form 483. ¶¶ 60, 61. The article concluded that Ocular was misleading investors by stating that their manufacturing was "in a fully developed mode" when the May 2017 Form 483 presented contrary evidence. ¶ 62. Also on this day, STAT published another article and asserted that the FDA could reject Dextenza because of product contamination found by an FDA inspector during a visit to Ocular's manufacturing facility. ¶ 9. On all this news, Ocular's share

price fell $3.06, or over 30%, over two trading days. ¶¶ 10, 89.

6. After Ocular's Dextenza NDA is Rejected for a Second Time, the Fraud is Fully Revealed

On July 12, 2017, Ocular received another CRL from the FDA rejecting Ocular's January 2017 NDA for Dextenza. ¶ 64. Ocular announced receipt of the CRL that same day, admitting that the refusal was based on "deficiencies in manufacturing processes and analytical testing related to manufacture of drug product for commercial production identified during a pre-NDA approval inspection of the Ocular [] manufacturing facility that was completed in May 2017." ¶ 90. On this news, Ocular's share price fell $0.93, or 12.24%, on July 12, 2017. ¶ 91.

Some months later, on December 15, 2017, the Company received a subpoena from the SEC indicating that the SEC was investigating Ocular for its practices relating to Dextenza. ¶ 65. In a December 22, 2017 press release, the Company admitted that the SEC subpoena requested "documents and information concerning Dextenza (dexamethasone insert) 0.4mg, including related communications with the FDA, investors and others." *Id.*

III. ARGUMENT

A. Applicable Standards Disfavor Defendants' Motion

To state a § 10(b) claim, Plaintiffs must allege: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005). These claims are subject to the pleading standards of the Private Securities Litigation Reform Act ("PSLRA") and Fed. R. Civ. P. 9(b), requiring allegations of fraud to be stated with particularity. 15 U.S.C. § 78u-4(b). The PSLRA "do[es] not require a plaintiff to plead evidence" of their claims. *In re Cabletron Sys., Inc.*, 311 F.3d 11, 33 (1st Cir. 2002).

On a motion to dismiss, "the complaint is construed in the light most favorable to

plaintiff and its allegations are taken as true." *Upjohn Co. v. Mova Pharm. Corp.*, 899 F. Supp. 46, 47 (D.P.R. 1995); *Mass. Ret. Sys. v. CVS Caremark Corp. ("Caremark")*, 716 F.3d 229, 237 (1st Cir. 2013) ("we accept as true all well-pleaded facts set forth in the complaint and draw all reasonable inferences therefrom in the pleader's favor."). Accordingly, in the First Circuit "the motion to dismiss for failure to state a claim is viewed with disfavor." *Upjohn*, 899 F. Supp. at 47. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Caremark*, 716 F.3d at 237. "The plausibility standard is not akin to a 'probability requirement[;]'" rather, a claim is "facially plausible if it is supported by factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

Therefore, to defeat a motion to dismiss, a complaint simply must contain "enough facts to raise a reasonable expectation that discovery will reveal evidence supporting the claims." *Fantini v. Salem State College*, 557 F.3d 22, 26 (1st Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007)). The Complaint adequately alleges that Defendants made material misrepresentations and omissions, and that they acted with extreme recklessness or actual knowledge regarding the same.[6] As such, Defendants' motion should be denied.

B. The Complaint Pleads Material Misrepresentations and Omissions Made During the Class Period

To plead falsity, Plaintiffs must identify "the specific statements rendered materially misleading" by the fraud alleged in the Complaint. *Cabletron*, 311 F.3d at 33-34. Falsity is alleged adequately "when plaintiff claims that defendant made 'an untrue statement of a material fact,' . . . or 'omitted to state a material fact necessary in order to make the statements made, in light of the circumstances in which they were made, not misleading.'" *Miss. Pub. Emp. Ret. Sys.*

[6] Defendants do not challenge, and thus concede, that all elements of a § 10(b) claim, other than falsity and scienter, are pled sufficiently.

v. Boston Sci. Corp., 523 F.3d 75, 85 (1st Cir. 2008) (quoting 15 U.S.C. §§78u-4(b)(1)(A) & 78u-4(b)(1)(B)). As discussed below, the Complaint sufficiently identifies the specific statements and omissions alleged to be materially false or misleading, as well as the reasons why they are so. *See* ¶¶ 67-80.

1. Defendants' Statements Attesting to Ocular's Compliance with cGMP Were Materially Misleading Because the Company Was *Not* in Compliance with Those Regulations

(a) The March 2016 Attestation to Ocular's cGMP Compliance

Contrary to their belated protestations, Defendants repeatedly misrepresented to investors that Ocular was cGMP compliant. Ocular's 2015 Form 10-K filed on March 10, 2016, stated that "for all our therapeutic product candidates using current good manufacturing practices, or cGMP, at our multi-product facility. . . ." *See* ¶¶ 67, 73. This statement was materially false and misleading because in fact Ocular was ***not*** in compliance with cGMP at the time that each of these representations were made, as evidenced by the two Form 483 issued by the FDA.

To be cGMP compliant, a company must meet the minimum requirements under Section 21 of the Code of Federal Regulations (¶ 27); if the FDA discovers objectionable conditions in a manufacturing facility, it will issue a Form 483 to document and communicate the observed deficiencies. ¶ 28. Compliance with cGMP is required to receive FDA approval of the commercialization of a drug product. ¶¶ 27-29, 45, 68.

Defendants misled investors regarding Ocular's cGMP compliance because they (1) received the February 2016 Form 483 that informed Defendants of Ocular's cGMP non-compliance, less than one month prior to filing the 2015 Form 10-K (¶ 5, 31, 32); and (2) received the July 2016 CRL *confirming* Ocular was *never* in cGMP compliance at any point after receiving the February 2016 Form 483 (¶ 45).

The February 2016 Form 483 listed ten inspectional observations documenting serious

deficiencies in Ocular's manufacturing process, essentially informing Defendants that Ocular was not cGMP compliant when they received the Form 483. ¶¶ 31-39. These known deficiencies made clear that Ocular's manufacturing processes and procedures would require significant and comprehensive changes in the manufacturing process, requiring months or years of effort, in order be in compliance with cGMP requirements. *E.g.*, ¶¶ 32, 33-35, 40. Thus, when Ocular filed its 2015 Form 10-K, *less than one month later*, it could not have been cGMP compliant, and therefore Defendants' statement that "all our [. . .] product candidates us[e] current good manufacturing practices, or cGMP" was materially false and misleading. *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002) ("the fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence" of fraud.).

This reasonable inference is reinforced by the fact that when the FDA rejected Ocular's NDA in July 2016, the CRL specifically raised concerns "pertain[ing] to deficiencies in the manufacturing process and controls identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility." ¶ 45. This direct link to the inspection giving rise to the February 2016 Form 483 further supports Plaintiffs' allegations that, at the time Defendants made the statements regarding cGMP compliance, Ocular was not cGMP compliant.[7]

Defendants argue that the FDA's issuance of Form 483 does not render the Company's

[7] Thus, as explained above, Plaintiffs do not rely solely on the FDA's 2016 CRL to allege that the Company was cGMP non-compliant in March 2016, contrary to Defendants' suggestion otherwise. Accordingly, Plaintiffs are at no risk of pleading "fraud-by-hindsight." MTD at 9. "The incantation of fraud-by-hindsight will not defeat an allegation of misrepresentations and omissions that were misleading and false *at the time they were made*." *In re Bear Stearns Companies, Inc. Sec., Deriv., & ERISA Litig.*, 763 F. Supp. 2d 423, 487 (S.D.N.Y. 2011) (emphasis added). That term simply does not apply when the conditions rendering the statements false or misleading exist at the time of the misstatements. *Hall v. The Children's Place Ret. Stores, Inc.*, 580 F. Supp. 2d 212, 228-29 (S.D.N.Y. 2008).

cGMP compliance statements false because Form 483s are "inspectional observations," rather than final Agency determinations of non-compliance. MTD at 8. Yet Plaintiffs do not allege, or rely on any allegation, that the Form 483s that Ocular received were final Agency determinations. Plaintiffs plead merely that the "inspectional observations" contained in the Form 483s were accurate observations of the objectionable conditions of Ocular's manufacturing operations. Plaintiffs therefore plead that those objectionable conditions rendered Ocular cGMP non-complaint. The Court must accept as true Plaintiffs' allegations that the conditions of Ocular's manufacturing operations were as the inspectors reported, and Plaintiffs allege that such conditions rendered the Company cGMP non-compliant at all relevant times.[8] *In re Sepracor, Inc. Sec. Litig.*, 308 F. Supp. 2d 20, 31 & n.4 (D. Mass. 2004) ("a motion to dismiss is not the appropriate method by which to test the accuracy of the facts alleged in the complaint.").[9]

(b) The March 2017 Attestation to Ocular's cGMP Compliance

In Ocular's 2016 Form 10-K filed on March 10, 2017 (the "2016 Form 10-K"), Defendants again misled investors with the same misrepresentation that "We fabricate . . . our therapeutic product candidates using current good manufacturing practices, or cGMP[.]" ¶ 73. At that time, not only had Defendants already received the February 2016 Form 483, which notified them of critical deficiencies in Ocular's manufacturing processes and procedures (¶ 31), but they also had received the FDA's rejection of Ocular's NDA in July 2016, citing the previously identified manufacturing deficiencies in the February 2016 Form 483. ¶ 45. During a time when Defendants should have been focused on improving Ocular's manufacturing

[8] ¶¶ 32 & n.2, 48 & n.3 (detailing each of the FDA quality assurance regulations, or cGMP, that the serious observations reported in the Form 483s violated).

[9] Moreover, while, as Defendants note (MTD at 8), Ocular disclosed the February 2016 Form 483 in its 2015 Form 10-K, Ocular failed to disclose the numerous damning inspectional observations in that Form 483 that rendered the Company patently cGMP non-compliant. For that reason and others, the 2015 Form 10-K further misled investors. ¶ 68.

processes and procedures per the FDA regulations, Ankerud, according to a CW,[10] expressly acknowledged that "he and the Company knew Ocular would be including batch records [. . .] *that would not meet FDA standards*." ¶ 46 (emphasis added). These events took place before Ocular filed its 2016 Form 10-K and clearly support the reasonable inference, as Plaintiffs allege, that, at that time, Ocular was still not in cGMP compliance, contrary to its public statements.

This reasonable inference is *confirmed* by the May 2017 Form 483, which repeated deficiencies previously documented by the FDA in the February 2016 Form 483. ¶¶ 48, 49; *compare, e.g.*, ¶ 39, *with* ¶ 55. The continued existence of manufacturing deficiencies from one Form 483 to the next supports the reasonable inference that Ocular was never in compliance with cGMP during the entire time period between the two FDA inspections. Finally, the May 2017 Form 483 also documented an observation related to non-compliant batches that dated back *as early as February 2016* and *as late as January 2017* (just two months prior to Ocular's 2016 Form 10-K filing). ¶¶ 50, 51, 53. These non-compliant batches directly link the February 2016 cGMP non-compliance through to the following year; indeed, the non-compliant batches were still in Ocular's manufacturing facility in May 2017, *after* the Company issued its 2016 Form 10-K. The allegations discussed above, taken in context, show that Defendants' statement regarding cGMP compliance in the 2016 Form 10-K was a material misstatement.

(c) Defendants' Disclosures Were Incomplete and Inadequate

Defendants claim that Plaintiffs' omissions allegations fail because "Ocular actually disclosed . . . the subject matter of the FDA's observations[,]" citing, for example, their explanation in the 2015 Form 10-K that the February 2016 Form 483 contained "inspectional observations focused on process controls, analytical testing and physical security procedures."

[10] Contrary to Defendants' arguments, the Complaint sufficiently establishes the CW's reliability with respect to Ankerud's statement regarding batch records. *See* Sec. III.D, *infra*.

MTD at 8, 10. Defendants fail to acknowledge that their summary "disclosure" did not actually publicly disclose the full extent of the massive problems in Ocular's manufacturing operations, and accordingly failed to disclose that: (1) Ocular was not cGMP compliant; and (2) it was highly unlikely that Dextenza would receive FDA approval on the PDUFA action dates. *Hill v. State Street Corp.*, 2011 WL 3420439 at *20-21 (D. Mass. Aug. 3, 2011) (cautionary disclosures made while simultaneously "assur[ing] investors that the portfolio and conduits' assets were high quality" did not defeat securities fraud claim where "some . . . disclosures simply failed to provide sufficient warning or detail, while others actually obscured as much as they revealed.").

Thus, Defendants find no refuge in their overly broad conclusion that "the securities law [sic] do not require further disclosure of the contents of the Form 483s." MTD at 11. Defendants' long string cite supporting this "conclusion" is full of inapposite and factually distinct cases that do not support such a rule.[11] A number of these cases turn on the materiality of a certain omitted fact, and materiality under the securities laws only require "a substantial likelihood that a reasonable investor would view" risks to the Company's ability to gain FDA approval "as having significantly altered the 'total mix' of information made available." *See Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1988). Here, investors would have viewed Ocular's ability to get NDA approval from the FDA by the two Class Period PDUFA target action dates differently if they had known about the numerous and far reaching deficiencies in Ocular's manufacturing processes and procedures. *Rihn v. Acadia Pharms. Inc.*, 2016 WL 5076147 at *5-*6 (S.D. Cal. Sept. 19, 2016) (a reasonable investor would have found the risk posed to the

[11] For example, in *In re Genzyme Corp.*, the alleged misrepresentations related to the company's general assurances regarding FDA approval (2012 WL 1076124, at *3, *5 (D. Mass. Mar. 30, 2012)), unlike here, where Defendants' statement regarding cGMP compliance was directly contradicted by the issuance of a Form 483, and investors, if they had known of the contents of the Form 483, would have assessed Ocular's cGMP compliance differently.

company's ability to timely complete a critical component of the NDA material).[12]

2. Defendants' Announcements of the Form 483s Were Materially Misleading Because They Misrepresented the Nature and Extent of the Inspection Deficiencies, Omitted Material Negative Facts Regarding Ocular's Manufacturing, and Concealed Material Risks to Ocular's Business

(a) November 9, 2016 Conference Call

On November 9, 2016, after the FDA rejected Dextenza's NDA, Defendants assured investors, in discussing Ocular's plans to resubmit and NDA for Dextenza in the near future that "we've adequately we think addressed the issues that [the FDA] raised." ¶ 71. The law is well-settled that "[w]hen a corporation does make a disclosure—whether it be voluntary or required—there is a duty to make it complete and accurate[, and that,] once made, [it] must not be 'so incomplete as to mislead.'" *Rosenbaum Capital LLC v. Boston Commc'ns Grp., Inc.*, 445 F. Supp. 2d 170, 175-76 (D. Mass. 2006) (internal citations and quotations omitted).[13] By addressing Dextenza's commercialization, Defendants were required to tell the whole truth. They did not.

In particular, investors had a right to know all relevant information received from the FDA (*i.e.*, the *specific, damning* observations in the February 2016 Form 483) in order to evaluate Defendants' guarantee themselves.[14] *Cf. In re Transkaryotic Therapies, Inc. Sec. Litig.*,

[12] And in fact, the sharp declines in Ocular's stock price following the disclosure of the fraud demonstrate that disclosure of the Form 483s' contents were material to investors. *Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000) ("the materiality of disclosed information may be measured post hoc by looking to the movement, in the period immediately following disclosure, of the price of the firm's stock.").

[13] *See also In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 258 (2d Cir. 2016) ("It is well-established precedent in this Circuit that once a company speaks on an issue or topic, there is a duty to tell the whole truth, even when there is no existing independent duty to disclose information" on the issue or topic.).

[14] Contrary to Defendants' assertions (MTD at 12), these statements are not mere "puffery." In determining puffery, a court must first consider "whether the statement is so vague, so general,

319 F. Supp. 2d 152, 160 (D. Mass. 2004) ("the failure to disclose the concerns raised in the highly negative Complete Review Letter. . . makes TKT's trumpeting of Replagal's efficacy arguably misleading."). As set forth above, to be in compliance with cGMP, Ocular would need to make numerous significant changes to its manufacturing operations, at great expense and delay, in order to gain FDA approval for Dextenza. ¶¶ 32, 40.

Defendants claim that their alleged misstatements from the November 9, 2016 earnings call are not actionable because they were mere expressions of opinion. MTD at 13. Defendants muddle the law when they assert that Plaintiffs must allege that Defendants "subjectively did not believe the statement or lacked any objective basis for believing it" in order to state a claim. As the Supreme Court held in *Omnicare, Inc. v. Laborers District Council Constr. Indus. Pension Fund*, 135 S. Ct. 1318 (2015), an opinion is actionable, regardless of the speaker's subjective belief, if the statement omits material facts about the issuer's . . . knowledge concerning a statement of opinion, and . . . those facts conflict with what a reasonable investor would take from the statement itself." *Id*. at 1329. Put differently, a statement of opinion is misleading if it does not "fairly align[] with the information in the issuer's possession at the time." *Id*.

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or so loosely optimistic that a reasonable investor would find it unimportant to the total mix of information." *Brumbaugh v. Wave Sys. Corp.*, 416 F. Supp. 2d 239, 250 (D. Mass. 2006). "[O]nly purely forward-looking statements are entitled to protection as 'mere puffery.' Statements of present or historical fact are not mere 'puffery.'" *In re Smith & Wesson Corp. Sec. Litig.*, 604 F. Supp. 2d 332, 342 (D. Mass. 2009). As "the recent trend is to consider expressions of corporate optimism carefully," courts must consider "whether the statement was also considered unimportant to the total mix of information by the market as a whole." *In re Boston Sci. Corp. Sec. Litig.*, 2011 WL 4381889, at *11 (D. Mass. Sept. 19, 2011), *aff'd*, 686 F.3d 21 (1st Cir. 2012). "[D]ismissals on this ground are increasingly rare[]" in this District. *Brumbaugh*, 416 F. Supp. 2d at 250 n.11. Here, as explained above, Sawhney's statement that Ocular had adequately addressed the FDA's observed deficiencies were highly material. Sawhney's statement was also in response to an analyst's question, demonstrating the materiality of his response. *W. Va. Pipe Trades Health & Welfare Fund* v. *Medtronic, Inc.*, 57 F. Supp. 3d 950, 970 (D. Minn. 2014) (courts have typically found otherwise vague statements to be actionable when they were made in response to a specific inquiry from an analyst or investor.").

Therefore, Plaintiffs need only allege facts showing that Defendants' assessments of the status of obtaining approval for Dextenza did not "fairly align with the information" in their possession at the time, which Plaintiffs have done here. Specifically, Plaintiffs allege that when the FDA rejected the Company's NDA in July 2016, the FDA specifically linked that rejection to outstanding manufacturing deficiencies it discovered earlier in February 2016. Defendants were unable to remedy the deficiencies cited by the FDA in the five months that passed the FDA's February 2016 inspection. Therefore, the information in their possession did not fairly align with their statement assuring adequate resolution of those deficiencies.[15]

(b) May 5, 2017 Conference Call

On a May 5, 2017 conference call, Defendants stated that the Company expected to be able to resolve the problems identified in the May 5, 2017 Form 483 "in a timely manner" (*i.e.*, by the July 19, 2017 PDUFA Action Date). ¶¶ 75-80. However, by May 5, 2017, Defendants knew, but failed to disclose, that the timing of the FDA approval was in serious jeopardy because of the repeated unresolved observations outlining serious deficiencies in Ocular's manufacturing process of Dextenza. Having chosen to communicate with investors, Defendants were obligated to make their disclosures materially "complete and accurate." *See Special Situations Fund III, L.P. v. Am. Dental Partners, Inc.*, 775 F. Supp. 2d 227, 240 (D. Mass. 2011); *Akamai Techs., Inc. v. Deutsche Bank AG*, 764 F. Supp. 2d 263, 267 (D. Mass. 2011).

Defendants claim that the false statements were merely "expressions of corporate optimism or opinion." MTD at 18. Attempting to assure investors that the manufacturing deficiencies will be resolved "in a timely manner" while concealing the conflicting known fact that the same deficiencies dating back to February 2016 were still present is actionable. *Yanek v.*

[15] The August 2016 letter from the FDA provides no refuge for Defendants. MTD at 14. The FDA's approval of Ocular's remediation plan is vastly different from an approval of Ocular's actual completion of remediation of the FDA-identified manufacturing deficiencies.

Staar Surgical Co., 388 F. Supp. 2d 1110, 1132 (C.D. Cal. 2005) (statements "assuring investors" while concealing adverse facts about FDA approval were actionable). Even opinions that the speaker believes to be true are misleading where the speaker "knowingly omits undisclosed facts tending seriously to undermine the accuracy of the statement." *Hill*, 2011 WL 3420439, at *23 (internal citation omitted). Here, Defendants omitted facts about the massive manufacturing problems Ocular was experiencing, and those facts seriously undermined the accuracy of Defendants' statements that the problems would be resolved "in a timely manner"—given the Company's manufacturing problems, there was no chance the problems would be resolved by the PDUFA date. ¶¶ 59, 75-80.

3. The Safe Harbor Does Not Insulate Defendants' Statements

Contrary to Defendants' arguments (MTD at 12, n.12; and 15), Defendants' statements in November 2016 and May 2017 do not qualify for safe harbor protection because they did not include "meaningful" cautionary language. 15 U.S.C. § 78u-5(c)(1)(A). "Vague or boilerplate disclaimers are insufficient to invoke safe harbor protection." *Sepracor*, 308 F. Supp. 2d 20, 34 (D. Mass. 2004) (quotations omitted). To be "meaningful," cautionary language must "adequately disclose both the risks involved and the assumptions upon which the optimistic, forward looking language is based." *Yanek*, 388 F. Supp. 2d at 1122. Defendants have the burden to show that the "cautionary language was not boilerplate and conveyed substantive information." *Slayton v. Am. Express Co.*, 604 F.3d 758, 772 (2d Cir. 2010).

In support of Defendants' assertions that they sufficiently warned investors about the expected resolution of the FDA's inspectional observations and the prospects for FDA approval of Dextenza, Defendants point to anodyne, boilerplate language that could apply to almost any drug company engaged in the process of seeking FDA approval. MTD at 16. For example:

> As a reminder, during today's call, we will be making certain forward-looking statements. . . . Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those discussed in the Risk Factors section of our most recent annual report[.] (*Id.*)

Such generic disclosures are wholly inadequate; once the FDA issued the May 2017 Form 483 with repeated and overlapping observations from the previous Form 483, the relevant risks to Ocular's shareholders were no longer the generic risks of potential delays, but actual and specific existing risks that materially threatened the Dextenza NDA and the drug's commercialization. *See, e.g*., *Washtenaw Cnty. Empls. Ret. Sys. v. Celera Corp*., 2012 WL 3835078, at *4 (N.D. Cal. Sept. 4, 2012) ("The safe harbor cannot protect cautionary statements made with superior knowledge that some of the potential perils identified have in fact been realized.")

The safe harbor also does not apply to Defendants' omissions. *Takara Trust v. Molex Inc.*, 429 F. Supp. 2d 960, 974 (N.D. Ill. 2006) ("it is axiomatic that the failure to make a statement cannot be forward-looking"); *In re Complete Mgmt. Inc. Sec. Litig.*, 153 F. Supp. 2d 314, 340 (S.D.N.Y. 2001) (stating that safe harbor "appl[ies] to forward-looking statements only, and not to material omissions or misstatements of historical fact."). This is true, "regardless of whether the statements thereby rendered misleading were forward-looking." *City of Providence v. Aeropostale, Inc.*, 2013 WL 1197755, at *12 (S.D.N.Y. Mar. 25, 2013). On May 5, 2017, when Defendants announced the receipt of the May 2017 Form 483, Defendants omitted that several observations either overlapped with, or expanded upon, previous observations in the February 2016 Form 483, showing Ocular never actually resolved all of the previously observed deficiencies. *See* Sec. II.C.4, *supra*. In other words, Defendants did not disclose existing manufacturing problems that made FDA approval of Dextenza highly unlikely, if not categorically impossible. No amount of cautionary verbiage could cure these omissions.

C. The Complaint Alleges a Strong Inference of Scienter

In a securities fraud action, a "plaintiff must prove that the defendant acted with scienter, 'a mental state embracing intent to deceive, manipulate, or defraud.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 46 (2011). Defendants possess the requisite scienter under §10(b) when they act either intentionally *or* with deliberate recklessness. *Boston Sci.*, 686 F.3d at 29 (holding that scienter may be demonstrated by showing that a defendant either "acted with fraudulent intent or knowing or reckless disregard of his obligation to disclose").

Scienter can be inferred from "indirect and circumstantial evidence." *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 195 (1st Cir. 1999). A plaintiff "may combine various facts and circumstances indicating fraudulent intent . . . to satisfy the scienter requirement." *Aldridge*, 284 F.3d at 82. The inquiry "is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 310, 322 (2007).

Dismissals based on scienter grounds are disfavored at the pleading stage because "we cannot hold plaintiffs to a standard that would effectively require them, pre-discovery, to plead evidence." *Boston Sci.*, 523 F.3d at 90 (citations omitted). "The inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the 'smoking-gun' genre, or even the 'most plausible of competing inferences.'" *Tellabs*, 551 U.S. at 324 (citation omitted). An inference of scienter is "strong" if it is "cogent and compelling" and "*at least as likely as* any plausible opposing inference." *Id.* at 324, 328 (emphasis in original). "[W]here there are equally strong inferences for and against scienter, *Tellabs* now awards the draw to the plaintiff." *ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 59 (1st Cir. 2008) (citing *Tellabs*, 551 U.S. at 324).

1. Defendants Knew About – and Recklessly Disregarded – the Material Deficiencies and Defects Observed in the Form 483s and their Importance to the Dextenza NDA

"[T]he fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter." *Aldridge*, 284 F.3d at 83 (scienter alleged when plaintiffs provided "a series of factual allegations relating to a combination of developments known to the company . . . that *could have* provided a basis for advance knowledge" of information contrary to public statements) (emphasis added).

Contrary to Defendants' argument (MTD at 26), the Complaint expressly alleges that throughout the Class Period, Defendants had actual knowledge of deficiencies and defects in the manufacturing process of Ocular's lead product candidate, Dextenza,[16] that rendered manufacturing of Dextenza non-cGMP-compliant (¶¶ 28, 29, 31, 32 & n.2, 48 & n.3).[17] Most obviously, *the Individual Defendants personally received* two Form 483s that documented in detail these profound and persistent manufacturing defects and deficiencies. The nature of these deficiencies was such that timely remedy would have been a tremendous undertaking for Ocular, and rendered the FDA's approval of an NDA for, and thus future of, Dextenza unlikely and uncertain. ¶¶ 33, 40. Yet, despite these known manufacturing deficiencies, and the palpable known risks posed to the Dextenza NDA as a result, Defendants continued to represent to investors throughout the Class Period that Ocular remained cGMP-compliant in its manufacture

[16] ¶¶ 30-39 (receipt of February 2016 Form 483 listing ten observations where the FDA found Ocular's manufacturing to be defective and deficient); 45 (July 2016 CRL rejecting Ocular's NDA application due to unresolved manufacturing deficiencies); 46 (admission that NDA resubmission would include batch records that would not meet FDA standards); 49, 50, 53-55 (May 2017 Form 483 included observations that repeated and expanded upon earlier observations, and other observations found that lots manufactured between the two Form 483s were not "systematically evaluated" and that almost half contained unknown and uninvestigated particulate matter, all of which indicated that manufacturing conditions were not improving).

[17] Which, as explained above, must be accepted as true on a motion to dismiss. *See* Sec. III.B.1(a), *supra*.

of Dextenza (¶¶ 42, 67, 73), and that Defendants were adequately addressing the FDA's criticisms required to be corrected prior to Dextenza's NDA approval (¶¶ 69, 71, 75, 77, 79).

Defendants argue that the Complaint does not sufficiently allege scienter because it merely alleges that the Defendants "must have known" information due to their titles and thus were "privy to" the material information at issue here. MTD at 26. To the contrary, the Complaint does not merely "generally aver . . . the defendant's 'knowledge' of material falsity [but instead] sets forth specific facts that make it reasonable to believe that defendant knew that a statement was false or misleading." *Maldonado v. Dominguez*, 137 F.3d 1, 9 (1st Cir. 1998). For instance, both the February 2016 and May 2017 Form 483s were directed and sent to Sawhney. ¶¶ 5, 98. Sawhney further represented to the FDA that he was "the most responsible person of the firm" for purposes of handling FDA communications (¶ 98), and he spoke frequently and directly to investors and the FDA about Ocular's response to the Dextenza "manufacturing items" raised by the FDA. ¶¶ 58, 69, 71; MTD Ex. B at 1. Accordingly, the Complaint's allegations regarding Sawhney's scienter are "at least as likely as any plausible opposing inference." *Tellabs*, 551 U.S. at 324, 328.

Similarly, Ankerud represented to the FDA that he was the person primarily responsible for "clinical operations, regulatory affairs, [and] quality assurance[,]" was Ocular's "Management Representative," and in the absence of the CEO Sawhney, was designated as the person to receive the FDA Form 483. ¶ 101. Further, during the Class Period, Ankerud served as Ocular's Executive Vice President of Regulatory, Quality, and Compliance, and was charged with ensuring that Dextenza, and the manufacturing process and facility that produced Dextenza, met applicable regulations, including cGMP. ¶¶ 97, 101. Ankerud also spoke to investors about Ocular's response to the May 2017 Form 483, and the resolution of those manufacturing defects

in producing Dextenza. ¶¶ 75, 77.

These detailed factual allegations support a cogent and compelling inference that Defendants knew and understood the nature of, or were deliberately reckless in not knowing, the importance of the observations in the Form 483s, and that these reported observations rendered Ocular non-cGMP-compliant. *See, e.g., Boston Sci.*, 523 F.3d at 91-92 (scienter inferred where defendant was "point person on TAXUS, and so he would presumably have been aware of the status of the company's 'ongoing monitoring' of 'old' TAXUS stents."); *In re Able Labs. Sec. Litig.*, 2008 WL 1967509, at *17 (D.N.J. Mar. 24, 2008) (requisite recklessness supported by defendants' positions as the "head of Quality Control," another "[h]aving oversight responsibility for the quality control and regulatory compliance functions of Able," and as CEO, who had received presentation of the FDA's inspection deviations).

Moreover, the Complaint alleges that Defendants purposely failed to follow through on, or recklessly did not appreciate, the significant undertaking that was required to satisfactorily resolve its manufacturing defects and deficiencies. ¶ 44. Defendants knew Dextenza's NDA would not be approved until Ocular was able to manufacture Dextenza in compliance with cGMP. ¶¶ 27-29, 45, 68. Indeed, during the Class Period, Defendants explained, "[s]atisfactory resolution of the manufacturing deficiencies identified" in the February 2016 Form 483 was required before the NDA may be approved (¶ 45; MTD Exs. B at 1, F at 17, 34) and that they had established a corrective action plan to appropriately resolve these manufacturing defects and deficiencies (¶¶ 43, 59, 69, 71, 75, 77, 79; MTD Ex. C at 1). These allegations amply demonstrate Defendants' knowledge both of what was required to resolve the observed manufacturing defects and the drastic implications should Ocular fail to resolve those issues.[18]

[18] These well-pled allegations further highlight the "absurdity' of Defendants' argument that

Yet, understanding the scope of this major undertaking, Defendants chose to understate the Form 483s' observations (¶¶ 43, 75), and assure investors the deficiencies were, and would be, successfully and timely resolved (¶¶ 69, 71, 75, 77, 79), while omitting material negative facts found in the observations that made timely resolution of these issues highly unlikely to support approval of the Dextenza NDA (¶¶ 44, 60, 62). These detailed allegations support a strong inference of scienter. *See Boston Sci.*, 523 F.3d at 87 ("Knowingly omitting material information is probative . . . of scienter."); *Yanek*, 388 F. Supp. 2d at 1131-32 (defendants' knowledge "of the Form 483, the problems noted in the Form 483, and their possible implications for approval of the ICL[,]" and their "failure to mention those issues in their statements responding to direct questioning about potential obstacles to FDA approval raises a strong inference that those statements were made with actual knowledge of their falsity.").

2. The Core Operations Doctrine Further Supports Scienter

Defendants' omissions and misrepresentations involved "facts critical to [Ocular's] core operations" which further supports an inference of scienter. *Crowell v. Ionics, Inc.*, 343 F. Supp. 2d 1, 19 (D. Mass. 2004) (quotations and internal alteration omitted); *Chalverus v. Pegasystems, Inc.*, 59 F. Supp. 2d 226, 235 (D. Mass. 1999) (same); *Aldridge*, 284 F.3d at 84 (scienter alleged where relevant product line was a "primary driver" of the company's growth).

The Complaint alleges that Dextenza was Ocular's *primary drug candidate* (¶¶ 3, 24, 102), and Ocular's ability to manufacture and sell Dextenza was of *key importance* to its business, strategy, and valuation. ¶ 102. Sawhney and Ankerud informed the FDA that they were the two most responsible persons with respect to Dextenza's manufacturing process and the

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scienter has not been alleged due to the conclusory "position" allegations (MTD at 26, 27). *See Reese v. Malone*, 747 F.3d 557, 580 (9th Cir. 2014) (the magnitude of the violation and contemporaneous evidence of management's awareness of the company's non-compliance made it "absurd" to suggest that management was not aware).

quality assurance as part of this process, and both spoke directly to investors about Ocular's efforts to resolve the manufacturing defects and deficiencies observed in the February 2016 and May 2017 Form 483s. *See, e.g.*, ¶¶ 58, 69, 71, 75, 77, 97, 98, 101; Sec. III.C.1, *supra*.

Also, Ocular was not a large business, with just 94 full-time employees around the start of the Class Period. MTD Ex. A. at 72. This further supports the inference that the Individual Defendants had hands-on knowledge of the prospects of Ocular's principal product. Thus, the far more cogent and compelling inference is that the Individual Defendants, the "most responsible" persons at Ocular, fully appreciated the danger of withholding from investors the serious nature of the manufacturing defects and the threat these defects had on Ocular's "core" drug product. *Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 709, 711 (7th Cir. 2008) ("exceedingly unlikely" that CEO did not know facts about the corporation's "most important" and "flagship" products, particularly where false statements "'emanated' directly from him."); *Mulligan v. Impax Labs.*, 36 F. Supp. 3d 942, 970 (N.D. Cal. 2014) (similar).[19]

3. The SEC Investigation Supports an Inference of Scienter

Although a government investigation alone is not sufficient to establish scienter, it is "one more piece of the puzzle, a series of circumstances that add up to a strong inference of scienter." *Washtenaw Cty. Employees Ret. Sys. v. Avid Tech., Inc.*, 28 F. Supp. 3d 93, 115 (D. Mass. 2014) (collecting cases in which government investigations were part of the scienter analysis). Here, the SEC is investigating Ocular for its practices relating to Dextenza, including Defendants' related communications with the FDA and with investors. ¶ 65. Taking a "holistic view" of the scienter allegations, the presence of the SEC investigation is yet another "piece of

[19] Defendants contend that the core operations doctrine is "irrelevant" because the Complaint does not allege a single particularized fact giving rise to Defendants' scienter – *i.e.*, that there is no "plus factor." MTD at 27. In so arguing, Defendants ignore the numerous facts and circumstances indicating fraudulent intent alleged throughout the Complaint. *See* Sec. III.C.1, *supra* (detailing the facts and circumstances giving rise to the requisite inference of scienter).

the puzzle" indicating scienter.

4. Viewed Holistically the Complaint Alleges a Strong Inference of Scienter

Defendants ignore the holistic approach mandated by the Supreme Court, improperly focusing on the sufficiency of individual scienter allegations standing alone (MTD at 25-28). *See Tellabs*, 551 U.S. at 326; *Cabletron*, 311 F.3d at 40 ("Each individual fact about scienter may provide only a brushstroke, but the resulting portrait [may satisfy] the requirement for a strong inference of scienter under the PSLRA."). When viewed "holistically," the inference that Defendants acted with scienter is at least as likely as any other inference. *Tellabs*, 551 U.S. at 328. Thus, the allegations taken as a whole give rise to a strong inference of scienter.

Aside from mentioning Sawhney's miniscule Class Period stock purchases, Defendants do not even attempt to offer a plausible inference of non-culpable conduct, let alone a non-culpable inference that is *more* compelling than Plaintiffs' allegations of conscious and reckless behavior. *See* MTD at 25-28. That in itself is sufficient for a finding of scienter.

5. The Lack of Insider Trading Does Not Negate Scienter

Defendants argue that the Complaint does not plead any facts showing that Defendants had a motive to commit fraud, and that Sawhney's purchase of 55,300 shares of Ocular stock during the Class Period exculpates his misconduct. MTD at 27-28. However, both the Supreme Court and the First Circuit have made it clear that neither motive allegations nor stock sales during the class period are required to meet the PSLRA scienter requirement. *Tellabs*, 551 U.S. at 310 ("The absence of a motive allegation . . . is not fatal for allegations must be considered collectively."); *Greebel*, 194 F.3d at 197-98 (The PSLRA "neither prohibits nor endorses the pleading of insider trading as evidence of scienter."); *cf. Crowell*, 343 F. Supp. 2d at 15 ("a recklessness argument by definition would not require a motive.").

Indeed, the First Circuit has "rejected any rigid formula for pleading scienter, preferring

to rely on a 'fact-specific approach'" that proceeds case by case. *Cabletron*, 311 F.3d at 38. Here, the Complaint pleads strong circumstantial (and direct) evidence of recklessness and/or conscious misbehavior; it is unnecessary to enhance these allegations with evidence of motive.

In any event, Sawhney's paltry purchases – representing just a 0.4% and 1.75% increase, respectively, to his overall Ocular holdings – hardly supports a "strong" competing inference cutting against *all* Defendants' scienter. Rather, it was "entirely reasonable for [Sawhney and Ankerud] to refrain from selling stock during the Class Period to avoid the appearance of wrongdoing." *Collier v. ModusLink Glob. Sols., Inc.*, 9 F. Supp. 3d 61, 74 (D. Mass. 2014).[20]

D. The Allegations in the Complaint Attributed to the Confidential Witness Are Reliable and Should be Credited Fully

In arguing that Plaintiffs have failed to allege falsity and scienter, Defendants attack the credibility of the information offered by a former Ocular employee, *i.e.*, that "Ankerud expressly acknowledged that he and the Company knew Ocular would be including batch records in the NDA resubmission that would not meet FDA standards" in its January 2017 NDA resubmission (¶ 46). MTD at 20-23, 27.

Plaintiffs allege sufficient facts to show the reliability of this confidential source and the corroboration of allegations by the facts alleged as a whole. *See Hill*, 2011 WL 3420439, at *13 ("The CWs' statements are more than just water cooler hearsay; they offer important reinforcement for inferences reasonably drawn from other allegations."). Defendants first criticize the CW for failing to provide his or her job duties and responsibilities. In encouraging this Court to require a detailed description of the CW's job details, Defendants rely solely on

[20] *See also, e.g.*, *Thomas v. Magnachip Semiconductor Corp.*, 167 F. Supp. 3d 1029, 1044 (N.D. Cal. 2016) ("there are several explanations for why an individual defendant would not sell stock even if she knew about false financial statements, such as a desire to avoid drawing the market's attention to the problem. Further, even if an individual who *knows* of company misstatements may on the whole be less likely to keep her stock, the same cannot be said of an individual who is merely deliberately reckless in failing to be aware of such misstatements.").

out-of-circuit authority. The First Circuit, however, credits information from confidential sources so long as they are "described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged . . . ." *Cabletron*, 311 F.3d at 29-30; *see also Collier*, 9 F. Supp. 3d at 73 ("the PSLRA's pleading requirement cannot be construed to mean that confidential witnesses, who are former employees of the [c]ompany, must recall all possible details from their former positions").

The Complaint here complies with the First Circuit's rule. It provides the CW's title, Regulatory Affairs Project Manager, and the length of the CW's employment, November 1, 2016 through around the end of February 2017. ¶ 46. Both the CW and Ankerud were charged with regulatory affair duties while employed at Ocular (¶¶ 46, 101). Further, the Company's Dextenza NDA resubmission was a core focus of the small Company at that time (*see* Sec. III.C.2, *supra*). This is sufficient to provide "enough detail to determine whether the plaintiff has an adequate basis for believing its allegations." *Hill*, 2011 WL 3420439, at *13.

Defendants also criticize the CW for the length of his or her employment at Ocular. However, "[a] witness need not have been at the company for [the] entire, or indeed any, of an asserted class period to have probative information[,]" *Simon v. Abiomed, Inc.*, 2014 WL 1413638, at *14 (D. Mass. Apr. 10, 2014). Regardless, the length of the CW's employment at Ocular does not affect his or her personal knowledge of Ankerud's highly damaging admission that "the NDA resubmission that would not meet FDA standards."

Unable to discredit the CW, Defendants next attempt to explain in great detail why Ankerud's admission has "no bearing" on every single challenged statement and omission. MTD at 21-23. In doing so, Defendants stretch the import of the CW allegation. Plaintiffs do not use the CW allegation to support the actionability of the November 9, 2016 and May 5, 2017

earnings call statements. Rather, the CW statement corroborates the other well-pled allegations establishing the actionability of the March 10, 2017 statement that Ocular adhered to cGMP in the manufacturing of its products, including Dextenza. *See* Sec. III.B.1, *supra*.

Defendants lastly argue that the batch records included in the NDA resubmission had nothing to do with cGMP compliance, and that Plaintiffs do not plead otherwise. MTD at 22, 23. Again, Defendants willfully misread the pleadings: the Complaint alleges that (1) cGMP compliance is required for NDA approval (¶¶ 28-29), (2) the February 2016 and May 2017 Form 483s observed that Ocular was not cGMP compliant at those times (¶¶ 28, 29, 31, 32 & n.2, 48 & n.3), and (3) observations in the latter Form 483 both repeated and expanded upon the earlier Form 483's concerns. These allegations support the reasonable inference that Ocular was never in cGMP compliance during the Class Period. Ankerud's admission just prior to the January 2017 NDA resubmission corroborates these allegations and further supports the inference that Ocular was not in cGMP compliance when it affirmed such compliance in March 2017.

E. The Complaint States a Claim for Control Person Liability

The Complaint adequately pleads a claim under § 10(b), and so a § 20(a) claim is also adequately alleged. *Collier*, 9 F. Supp. 3d at 76-77 (where a primary claim was stated, control person liability was also alleged sufficiently).

IV. CONCLUSION

Lead Plaintiffs respectfully request that the Court deny Defendants' motion.[21]

[21] In the event that the motion to dismiss is granted in whole or in part, Plaintiffs respectfully request leave to amend. *See, e.g.*, *In re Cytyc Corp.*, 2005 WL 3801468, at *29 (D. Mass. Mar. 2, 2005) (granting leave to amend and "allowing plaintiffs an opportunity to replead consistent with the rulings made in this opinion").

Dated: September 4, 2018

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CERTIFICATE OF SERVICE

I, Kara M. Wolke, hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on September 4, 2018.

s/ Kara M. Wolke
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